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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,261	12/03/2003	Herbert W. Harris	18184-0004 US	7783

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DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,261	HARRIS ET AL.	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Group I, claim(s) 1-12, are drawn to a pharmaceutical composition comprising a pharmaceutically acceptable carrier and 1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7-methoxy-8-hydroxy-5H-2,3-benzodiazepine , classified in class 540, subclass 569.

II. Group II, claim(s) 13-32, are drawn to a method of treating, or preventing or delaying the onset of an leukotriene B_4-mediated inflammatory disorder comprising the composition according to Claim 1, 2, 7, or 12 classified in class 540, subclass 569, class 514, subclass 886, class 517, subclass 903, class 514, subclass 830, class 514, subclass 919, and class 514, subclass 914 for example.

III. Group III, claim(s) 33-53, are drawn to a method of treating an adenosine-mediated disorder comprising administration of the composition according to Claim 1, 2, 7 or 12, classified in class 540, subclass 569, class 514, subclass 802, class 514, subclass 914, class 514, subclass 869, and class 514, subclass 826 for example.

+ 55

IV. Group IV, claim(s) 54, drawn to a method of enhancing wound healing comprising administration of the composition according to Claim 1, classified in class 540, subclass 569 and numerous subclasses within class 514 for example.

V. Group V, claim 56-57, are drawn to a method of inducing gastrointestinal relaxation comprising administration of the composition according to claim 1, classified in class 540, subclass 569, class 514, subclass 841, class 514, subclass 843, class 514, subclass 886, class 514, subclass 906, and class 514 subclass 892 for example.

VI. Group VI, claim 58, drawn to a method of preventing, reducing or delaying the onset of myelosuppression associated with cytotoxic chemotherapy or ionizing radiation therapy comprising administration of the composition according to Claim 1, classified in class 540, subclass 569, class 514, subclass 917, class 514, subclass 908, and class 514, subclass 885 for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical composition of Group I could be used to treat an adenosine-mediated disorder.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. Group I and II are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups I and II have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical composition of Group I could be used to treat the onset of a leukotriene B_4-mediated inflammatory disorder.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group III, restriction for examination purposes as indicated is proper. Group I and III are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups I and III have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Groups I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical composition of Group I could be used for treating the onset of a leukotriene B_4-mediated inflammatory disorder.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group IV, restriction for examination purposes as indicated is proper. Group I and IV are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature

databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups I and IV have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Groups I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical composition of Group I could be used for treating the onset of a leukotriene B_4-mediated inflammatory disorder.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group V, restriction for examination purposes as indicated is proper. Group I and V are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups I and V have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Groups I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical composition of Group I could be used for treating the onset of a leukotriene B_4-mediated inflammatory disorder.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group VI, restriction for examination purposes as indicated is proper. Group I and VI are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups I and VI have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Group II and Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group II discloses the method of treating an leukotriene B_4-mediated inflammatory disorder which is unrelated

to the method disclosed in Group III of treating an adenosine-mediated disorder. The disorders disclosed in Group II and Group III are mediated by two different compounds. In Group II, the disorder is mediated by leukotriene B_4, which is a lipid compound whereas the disorder in Group III is mediated by adenosine, which is a nucleoside. Therefore, the disorders of Group II and Group III are mediated at two different sites of action, which can result in different drugs and hence different responses to the drug. Additionally, the leukotriene B_4-mediated disorders are associated with inflammation whereas adenosine-mediated disorders are associated with various other disorders such as neurological disorders and heart failure. Therefore, the disorders of Group II and Group III would have different therapeutic uses and modes of action.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group III, restriction for examination purposes as indicated is proper. Group II and III are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups II and III have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Group II and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group II discloses the method of treating an leukotriene B_4-mediated inflammatory disorder which is unrelated to the method disclosed in Group IV of enhancing wound healing. The disorder disclosed in Group II and enhancement of wound healing in Group IV can be mediated differently. In Group II, the disorder is mediated specifically by leukotriene B_4, which is a lipid compound whereas the enhancement of wound healing in Group IV can be mediated by different pathways. Therefore, the disorders of Group II and Group IV can be mediated at two different sites of action, which can result in different drugs and hence different responses to the drug. Additionally, the leukotriene B_4-mediated disorders are associated with inflammation whereas the enhancement of wound healing is broad and can be associated with any type of injury or disorder (i.e. wounds caused by the disorder). Therefore, Group II and Group IV have different therapeutic uses and possible modes of action.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group IV, restriction for examination purposes as indicated is proper. Group II and IV are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups II and IV have been appropriately restricted on the

basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Group II and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group II discloses the method of treating an leukotriene B_4-mediated inflammatory disorder which is unrelated to the method disclosed in Group V of inducing gastrointestinal relaxation. The disorder disclosed in Group II and Group V can be mediated differently. In Group II, the disorder is mediated specifically by leukotriene B_4, whereas the induction of gastrointestinal relaxation in Group V can be mediated by different pathways. Therefore, the disorders of Group II and Group V can be mediated at two different sites of action, which can result in different drugs and hence different responses to the drug. Additionally, the leukotriene B_4-mediated disorders are associated with inflammation whereas the induction of gastrointestinal relaxation can be associated with several types of disorders such as constipation and irritable bowl syndrome. Therefore, Group II and Group V have different therapeutic uses and possible modes of action.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group V, restriction for examination purposes as indicated is proper. Group II and V are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a

search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups II and V have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Group II and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group II discloses the method of treating an leukotriene B_4-mediated inflammatory disorder which is unrelated to the method disclosed in Group VI of preventing, reducing or delaying the onset of myelosuppression associated with cytotoxic chemotherapy or ionizing radiation therapy. The disorder disclosed in Group II and Group VI can be mediated differently. In Group II, the disorder is mediated specifically by leukotriene B_4, whereas the prevention, reduction or delayed onset of myelosuppression associated with cytotoxic chemotherapy or ionizing radiation therapy can be mediated by different pathways. Also, leukotriene B_4 disorders do not have to be associated with cytotoxic chemotherapy or ionizing radiation therapy. Therefore, the disorders of Group II and Group VI can be mediated at two different sites of action, which can result in different drugs and hence different responses to the drug. Additionally, the leukotriene B_4-mediated disorders are associated with inflammation whereas the prevention, reduction

or delayed onset of myelosuppression is associated with cytotoxic chemotherapy or ionizing radiation therapy specifically. Therefore, Group II and Group VI have different therapeutic uses and possible modes of action.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group VI, restriction for examination purposes as indicated is proper. Group II and VI are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups II and VI have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Group III and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group III discloses a method of treating adenosine-mediated disorders, which is unrelated to the method disclosed in Group IV of enhancing wound healing. The disorders disclosed in Group III and Group IV can be mediated differently. In Group III, the disorder is mediated specifically by adenosine, which is a lipid compound whereas the enhancement of wound healing in Group IV can be mediated by different pathways. Therefore, the

disorders of Group III and Group IV can be mediated at two different sites of action, which can result in different drugs and hence different responses to the drug. Additionally, the adenosine-mediated disorders are associated with various other disorders such as neurological disorders and heart failure, whereas the enhancement of wound healing is broad and can be associated with any type of injury or disorder (i.e. wounds caused by the disorder). Therefore, Group III and Group IV have different therapeutic uses and possible modes of action.

Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group IV, restriction for examination purposes as indicated is proper. Group III and IV are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups III and IV have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Group III and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group III discloses a method of treating adenosine-mediated disorders, which is unrelated to the method

disclosed in Group V of inducing gastrointestinal relaxation. The disorder disclosed in Group III and Group V can be mediated differently. In Group III, the disorder is mediated specifically by adenosine, whereas the induction of gastrointestinal relaxation in Group V can be mediated by different pathways. Therefore, the disorders of Group III and Group V can be mediated at two different sites of action, which can result in different drugs and hence different responses to the drug. Additionally, the adenosine-mediated disorders are associated with various other disorders such as neurological disorders and heart failure, whereas the induction of gastrointestinal relaxation can be associated with several types of disorders such as constipation and irritable bowl syndrome. Therefore, Group III and Group V have different therapeutic uses and possible modes of action.

Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group V, restriction for examination purposes as indicated is proper. Group III and V are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups III and V have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Group III and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group III discloses a method of treating adenosine-mediated disorders, which is unrelated to the method disclosed in Group VI of preventing, reducing or delaying the onset of myelosuppression associated with cytotoxic chemotherapy or ionizing radiation therapy. The disorder disclosed in Group III and Group VI can be mediated differently. In Group III, the disorder is mediated specifically by adenosine, whereas the prevention, reduction or delayed onset of myelosuppression associated with cytotoxic chemotherapy or ionizing radiation therapy can be mediated by different pathways. Also, adenosine disorders do not have to be associated with cytotoxic chemotherapy or ionizing radiation therapy. Therefore, the disorders of Group III and Group VI can be mediated at two different sites of action, which can result in different drugs and hence different responses to the drug. Additionally, the adenosine-mediated disorders are associated with various other disorders such as neurological disorders and heart failure, whereas the reduction or delayed onset of myelosuppression is associated with cytotoxic chemotherapy or ionizing radiation therapy specifically. Therefore, Group III and Group VI have different therapeutic uses and possible modes of action.

Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group VI, restriction for examination purposes as indicated is proper. Group III and VI are not identically classified under the

U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups III and VI have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Group IV and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group IV discloses a method of enhancing wound healing, which is unrelated to the method disclosed in Group V of inducing gastrointestinal relaxation. The disorders disclosed in Group IV and Group V can be mediated differently. In Group IV, enhancement of wound healing can be mediated by different pathways, whereas the enhancement of wound healing in Group V can also be mediated by different pathways. Therefore, the disorders of Group IV and Group V can be mediated at two different sites of action, which can result in different drugs and hence different responses to the drug. Additionally, the enhancement of wound healing is broad and can be associated with any type of injury or disorder (i.e. wounds caused by the disorder), whereas the induction of gastrointestinal relaxation can be associated with several types of disorders such as

constipation and irritable bowl syndrome. Therefore, Group IV and Group V have different therapeutic uses and possible modes of action.

Because these inventions are distinct for the reasons given above and the search required for Group IV is not required for Group V, restriction for examination purposes as indicated is proper. Group IV and V are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups IV and V have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Group IV and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group IV discloses a method of enhancing wound healing, which is unrelated to the method disclosed in Group VI of preventing, reducing or delaying the onset of myelosuppression associated with cytotoxic chemotherapy or ionizing radiation therapy. The disorders disclosed in Group IV and Group VI can be mediated differently. In Group IV, enhancement of wound healing can be mediated by different pathways, whereas the prevention, reduction or delayed onset of myelosuppression associated with cytotoxic

chemotherapy or ionizing radiation therapy can also be mediated by different pathways. Therefore, the disorders of Group IV and Group VI can be mediated at two different sites of action, which can result in different drugs and hence different responses to the drug. Additionally, the enhancement of wound healing is broad and can be associated with any type of injury or disorder (i.e. wounds caused by the disorder), whereas the reduction or delayed onset of myelosuppression is associated with cytotoxic chemotherapy or ionizing radiation therapy specifically. Therefore, Group IV and Group VI have different therapeutic uses and possible modes of action.

Because these inventions are distinct for the reasons given above and the search required for Group IV is not required for Group VI, restriction for examination purposes as indicated is proper. Group IV and VI are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups IV and VI have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions of Group V and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group V, discloses a

method of inducing gastrointestinal relaxation which is unrelated to the method disclosed in Group VI of preventing, reducing or delaying the onset of myelosuppression associated with cytotoxic chemotherapy or ionizing radiation therapy. The disorders disclosed in Group V and Group VI can be mediated differently. In Group V, inducing gastrointestinal relaxation can be mediated by different pathways, whereas the prevention, reduction or delayed onset of myelosuppression associated with cytotoxic chemotherapy or ionizing radiation therapy can also be mediated by different pathways. Therefore, the disorders of Group V and Group VI can be mediated at two different sites of action, which can result in different drugs and hence different responses to the drug. Additionally, the induction of gastrointestinal relaxation can be associated with several types of disorders such as constipation and irritable bowl syndrome, whereas the reduction or delayed onset of myelosuppression is associated with cytotoxic chemotherapy or ionizing radiation therapy specifically Therefore, Group V and Group VI have different therapeutic uses and possible modes of action.

Because these inventions are distinct for the reasons given above and the search required for Group V is not required for Group VI, restriction for examination purposes as indicated is proper. Group V and VI are not identically classified under the U.S. Patent Classification guidelines, thus to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases will be extensive and will not overlap thus presenting a search burden to be searched together. Thus Groups V and VI have been appropriately restricted on the

basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call to the attorney is not required where 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since this restriction requirement is considered complex, a call to the attorney for telephone election was not made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER